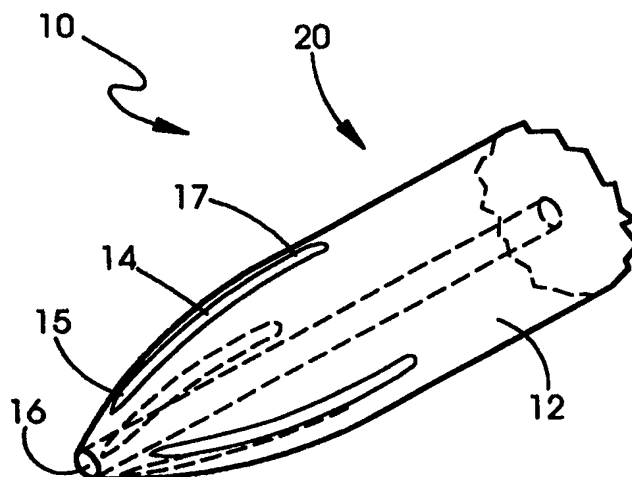




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b> <b>A61B 17/22</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 99/00060</b> <b>(43) International Publication Date:</b> 7 January 1999 (07.01.99)
<b>(21) International Application Number:</b> PCT/US98/13382 <b>(22) International Filing Date:</b> 26 June 1998 (26.06.98)  <b>(30) Priority Data:</b> 08/882,953                      26 June 1997 (26.06.97)                      US  <b>(71) Applicant:</b> ADVANCED CORONARY INTERVENTION [US/US]; Suite 101, 2 Inverness Drive Esat, Englewood, CO 80112 (US).  <b>(72) Inventors:</b> JANSSEN, W., Michael; Suite 101, 2 Inverness Drive East, Englewood, CO 80112 (US). McGARRY, Michael, C.; 3140 S. Race Street, Englewood, CO 80110 (US). STOCKMOE, Scott; 704 Paschal Drive, Lafayette, CO (US).  <b>(74) Agent:</b> WEINBERG, Peter, F.; Davis, Graham & Stubbs LLP, Suite 4700, 370 17th Street, P.O. Box 185, Denver, CO 80201-0185 (US).		<b>(81) Designated States:</b> CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> ELECTROSURGICAL CATHETER FOR RESOLVING OBSTRUCTIONS BY RADIO FREQUENCY ABLATION  <b>(57) Abstract</b> <p>A method and device (10) resolve occlusive deposits in a tubular passage of a subject by radio frequency ablation. The device (10) has a distal end (20) which is inserted within, along the lumen of a tubular body member, and may be manipulated therethrough to a desired position where the device will be operated. The device (10) includes an elongated flexible hollow tube (12) having a distal end, a proximal end, and a diameter smaller than the diameter of the tubular body member into which the device is being inserted. A number of electrodes (14) adjacent the distal end of the device, capability for selectively supplying radio frequency electrical current to at least one of said electrodes (14), and capability such as an inflatable balloon (30) for radially positioning the electrodes (14) with respect to the tube. Another embodiment includes electrodes (14) at varying radial positions so that at least one of such electrodes (14) will be capable of ablating material at varying positions within the lumen.</p>		



***FOR THE PURPOSES OF INFORMATION ONLY***

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

**ELECTROSURGICAL CATHETER FOR RESOLVING  
OBSTRUCTIONS BY RADIO FREQUENCY ABLATION**

5

**FIELD OF THE INVENTION**

The invention relates to a device and method for resolving or removing obstructions from a lumen within the body of a patient, such as removing atherosclerotic plaque build-up in an artery in order to improve blood flow. The device consists of an electrosurgical catheter which has a plurality of electrode sites, each capable of selectively resolving obstructions via radio frequency ("RF") ablation between the electrodes and the obstructions. The current generated at the selected electrode is modulated so that the obstructions are resolved without creating significant amounts of residue.

15

**BACKGROUND OF THE INVENTION**

Various angioplasty techniques have been in use for several years. Typically, a catheter is introduced into the body through an artery in the leg or arm and threaded into the artery or blood vessel that has restricted blood flow due to the build-up of atherosclerotic plaque. Obstructions are also removed from other tissue lumens, such as the fallopian tubes and genital-urinary tract and intestines. The most common technique in current practice is balloon angioplasty. The catheter is positioned within, for example, a subject artery, and has a deflated balloon at its tip. The balloon is inflated within the artery and the expansion of the balloon is designed to press the plaque into the artery wall or, if no plaque is present, press directly into the arterial wall. Balloon angioplasty does not remove plaque; instead, it stretches the arterial wall to increase the diameter of artery. Unfortunately, balloon angioplasty has several failings and a relatively high complication rate. For instance, the artery may be ruptured if the balloon stretches the artery beyond its elastic capabilities. Further, the artery may shrink, either relatively quickly or over a longer period of time, because the same elastic qualities of an artery that allow it to be stretched also cause the artery to contract after the removal of the stretching force.

25  
30

Atherosclerotic plaque build-up can exist in a number of different forms. The plaque can be quite hard and scaly, or more fatty and pliable. The areas of plaque

accumulation are generally not symmetrically located at a particular point in the artery, rather adhering to only portions of the artery walls.

Considerable efforts have been directed toward finding improved means to perform angioplasty procedures. Numerous devices recently have been described that  
5 utilize the application of heat to resolve atherosclerotic plaque. See for example, U.S. Patent Nos. 4,654,024 of Crittendon *et al.* and 4,748,979 and 4,672,962 of Hershenson. The most extensive research concerning the use of heat to resolve atherosclerotic plaque has been directed toward the area of laser angioplasty techniques. In most laser angioplasty devices the laser is used simply to supply heat to  
10 the tip of the catheter. See for example, U.S. Patent Nos. 4,784,133 of Mackin; 4,685,458 of Lechrone; 4,770,653 of Shturman; 4,662,368 and 4,773,413 of Hussein; and 4,732,448 and 4,641,912 of Goldenberg.

The various angioplasty techniques described in most of the literature uniformly fail to address the asymmetric disposition of the plaque within the artery. In most  
15 cases, the tip of the angioplasty catheter acts as if the plaque consists of a uniform symmetric coating on the interior wall of the artery. Particularly in those techniques which use something other than pressure to manipulate the plaque, the resolving forces are applied indiscriminately to the plaque and to the healthy tissue within the artery.

Radio frequency ablation to cut or cauterize tissue as a medical procedure is  
20 common in the prior art. There are two basic classes of electrosurgical devices. Monopolar devices consist of a high-frequency electrical (generally RF) generator, an ablating electrode or needle, and a patient plate. The patient plate is attached to the body of the patient, and acts as the return electrode for completion of the RF circuit. Ablation occurs due to the RF current directed from the electrode to the patient's body  
25 tissue. The shape of the ablating electrode concentrates the RF energy, thus creating high temperatures within the body tissue. Appropriate modulation of the frequency determines whether cutting or cauterizing will occur. The relatively larger surface area of the patient plate, which is in contact with the patient's body, prevents the return current flow from concentrating at one point. This lower current density prevents the  
30 RF current from burning the patient as the current exits the body.

There are also several bipolar electrosurgical devices described in the prior art. Bipolar devices consist of a high frequency electrical generator and an instrument that

contains both the delivery and return electrodes. RF ablation occurs between the two self-contained electrodes of the instrument. The bipolar electrosurgical devices of the prior art are generally inadequate due to the conditions necessary to create bipolar ablation. The most fundamental difficulty is that bioactive electrodes must have a roughly equal voltage drop at both the delivery and return electrodes. The high power current required in order to achieve bipolar ablation often causes extraneous sparking, particularly when there is unequal contact with the surrounding tissue.

The extension of known electrosurgical processes--utilizing RF ablation--to angioplasty techniques has been relatively unexplored. A disclosure of a monopolar electrosurgical catheter for use in resolving atherosclerotic plaque is found in U.S. Patent No. 4,682,596 of Bales. The monopolar and bipolar devices in Bales describe a hollow catheter with a hollow tip member. Only one potential electrode, at the catheter tip, is envisioned by the Bales patent. Bales briefly describes the utilization of variously modulated wave forms in order to resolve atherosclerotic plaque, and the application of high power levels while minimizing the creation of excessive amounts of heat. However, means are included for removing residue from the plaque destruction site, indicating that the modulation is not optimal. It would be desirable to destroy the plaque in such a manner so as to eliminate significant residue formation.

An article by Cornelius J. Slager et al. in the Journal of the American College of Cardiology entitled "Vaporization of Atherosclerotic Plaque by Spark Erosion" (June 1985, pp. 1382-86) describes the use of a bipolar RF catheter. Again, there is a single ablating electrode. The RF is modulated, but not so as to optimize ablation. Synchronous transmission of energy with cardiac contraction is employed in order to minimize the disruption of electrical rhythms in the heart.

U.S. Patent No. 4,643,186 of Rosen describes an "antenna" type bipolar RF sparking catheter for use in angioplasty. The delivery and return electrodes are configured in such a way that the electrodes terminate together to form an "antenna." When current is supplied to the antenna, RF sparking will occur. The addition of balloon means encapsulating the sparking antenna is also described. Rosen discloses coating the interior surface of such balloons in order to supply some control over the direction of sparking. Such directional manipulation can only be accomplished before

the catheter is introduced into the patient's body. No means are disclosed for directing the random sparking of the "antenna" once introduced into the desired artery.

An example of an asymmetrically shaped electrode or energy applicator is seen in U.S. Patent No. 4,311,154 of Sterzer. The Sterzer patent discloses a device to be used in the treatment of a cancerous tumor with high temperatures, known as hypothermia. Sterzer describes a device for hypothermic treatments utilizing microwave energy so that heat radiates nonsymmetrically from the surface of the instrument. Sterzer does not utilize RF ablation and, like the Rosen patent, does not enable directing the energy once the device is in place within the body.

The examples discussed above where RF ablation has been used for the resolution of atherosclerotic plaque employ relatively unsophisticated means. RF energy is a very powerful and intense force to concentrate within the human body. Only recently, means for effectively harnessing the vast potential of RF ablation angioplasty have been disclosed. U.S. Patent No. 5,454,809 of Janssen describes an electrosurgical catheter and method for resolving atherosclerotic plaque using RF current emitted from an electrode in close proximity to an occlusive deposit, and is incorporated herein by reference.

Still, there is another problem encountered in the devices disclosed by the prior art may be attributed to the non-uniformity of the way in which the atherosclerotic plaque builds up on the arterial wall. As the catheter moves through the arterial site of the atherosclerotic plaque, it is not uncommon for the direction of the catheter's movement to be shifted by contact with plaque, the flow of fluid within the artery, or by other means. The catheter may be shifted from a centered position within the tubular passage to a position where the device either may or may not be in contact with the arterial wall. Danger to the patient arises when ablation is attempted when the device is not either immediately adjacent or within an acceptable distance from the occlusive material. In this scenario, the RF may spark from the electrode to the wall, either injuring the patient or, at the least, failing to effectively ablate the plaque.

Some known devices manipulate the positioning of a catheter within the arterial site; however, in general these devices are intended to move an apertured section of a housing around the plaque to better effect slicing of the plaque by a cutlery blade. For example U.S. Patent No. 5,222,966 of Perkins et al. discloses a vascular catheter

which includes a flexible catheter body having proximal and distal ends and an elongate housing secured to the distal end of the catheter body. An interactional device is disposed on one side of the housing, and at least two spaced inflatable chambers are located on the other side of the housing, generally at the proximal and distal ends respectively. The inflatable chambers may be expanded simultaneously or separately, and the spaced positioning of the chambers provides for stable positioning of the housing during atherectomy procedures, imaging procedures and the like. Reissue Patent No. Re. 33,569 of Gifford, III et al. discloses an atherectomy device comprising a cutter mounted in a cylindrical housing having a cutout on one side thereof at the distal end of a catheter. The catheter has a single luminal opening and a flexible drive cable for operating the cutter movement through the opening. An inflatable balloon is positioned outside the housing opposite the cutout, and a medium for inflating the balloon is introduced through the luminal opening of the catheter.

U.S. Patent No. 5,071,425 of Gifford III et al. also discloses an atherectomy device having an apertured portion on one side of the housing and an inflatable balloon on the other side of the housing. The device includes a transparent lumen for providing inflation medium to an inflatable balloon. A dual lumen flexible tube includes an opaque flexible torque member in the first lumen, while the second lumen serves as an inflation lumen. The distal end of the inflation lumen is expanded to define the balloon, and no seals are needed between the balloon and the inflation lumen.

U.S. Patent No. 5,078,717 of Parins et al. discloses an RF catheter having electrodes that may bow outward from the catheter to increase its effective diameter. However, the electrodes may not be selectively activated, and no mechanism is provided for resolving obstructions that are not symmetrically formed within a lumen.

As evidenced by the prior art, catheters for resolving obstructions within a lumen are limited in their ability to selectively ablate only a section of the lumen. As previously mentioned, the device may become too distant to the arterial wall to contact or nearly contact the occlusive deposit, thereby rendering RF ablation difficult or even dangerous. The desired catheter thus includes means for effectively placing the electrodes in contact with the occlusive tissue in instances where the tubular passage is significantly wider than the diameter of the catheter.

### SUMMARY OF THE INVENTION

This invention relates to an improved device for the ablation or resolution of undesirable obstructions that may develop within the body of a patient, using RF ablation. The present invention adapts an electrosurgical electrode so that it may be incorporated into a catheter that may be manipulated to the precise obstruction site within the body of a patient. One common obstruction is atherosclerotic plaque that accumulates within blood vessels. The present invention also has application to obstructions such as mucous; all types of plaque such as fatty plaque, fibrous plaque, and calcific plaque; fibrotic material; blood clots; and other types of obstructions. These obstructions may develop within the various lumens of the body, such as coronary, renal, neurological, and periphery arteries and veins; the fallopian tubes and other lumens of the genital-urinary tract; intestines; bile ducts; and any other lumen or duct within the body. Of course, not all types of obstructions commonly occur within all types of lumens. The RF catheter of the present invention further incorporates a segmented head, so that it is possible to control nonsymmetrical emission of an RF charge from a plurality of electrodes.

The device of the present invention allows for greater control and precision when utilizing the emission of an RF charge to resolve obstructions. An embodiment of the invention may further include real time visualization techniques, such as may be provided by ultrasound or fiber-optics. The use of a segmented, positionable catheter head, what has been a somewhat random ablation technique may now be actively directed towards the obstruction site within a lumen.

Selective activation of one or more electrodes allows RF energy to be directed only towards the occlusive material, so that no or minimal energy is directed towards an unoccluded lumen wall. By employing increased energy, the material causing the obstruction may be completely, or almost completely, vaporized. The material constituting the obstruction may be reduced to such fine particles that removal of residue from the plaque resolution site is unnecessary. Once the obstruction has been partially removed from a site, the electrodes may be repositioned so that they maintain close contact with the remaining obstruction material.

The catheter device of the present invention may have an elongate flexible hollow body that has at least one open lumen capable of delivering fluids to the obstruction site. Also, implements such as a guide wire may be directed through this lumen or lumens so that the catheter may be guided. At the distal end of the device,  
5 there is a plurality of emitters or electrodes spaced about the exterior circumference of the generally cylindrical catheter device. The RF energy transmitted to the distal end of the catheter may be selectively applied to any one of the various electrodes. Visualization of the artery may determine which wall or walls of the artery contain the plaque build-up to be resolved and will determine which electrode should be activated.

10 The invention also includes means for radially positioning the electrodes within the lumen. Several methods for accomplishing this are described. The catheter may include a balloon located near the electrodes, so that inflating or deflating the balloon repositions the electrodes. Or, a wire or cam may be projected from the catheter to push off the lumen, and thereby change the position of the catheter and the electrodes.  
15 Propulsion jets and other methods may also be used to change the catheter position. Or, the catheter may include a number of electrodes at varying distances from the catheter axis, either fixed or slidably mounted to sleeves. The specific method used may depend on the specific catheter application and such factors as the degree of tissue sensitivity and the size of lumen. However, the purpose is the same in each  
20 embodiment--to insure that the electrodes maintain close contact with the occlusion material.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective isometric view of the distal end of an embodiment of the present invention.

FIG. 1A is a perspective isometric view of an alternate distal end of an  
5 embodiment of the present invention.

FIG. 1B is a perspective isometric view of the distal end of an embodiment of the present invention with a grounding electrode.

FIG. 2 is a schematic view of a monopolar embodiment of the present invention.

10 FIGS. 2A, 2B, and 2C are radial cross sectional views of the distal end of an embodiment of the present invention within a partially obstructed lumen.

FIG. 3 is a longitudinal sectional view of the embodiment of the invention shown in FIG. 1.

FIG. 4 is a distal end view of the device shown in FIG. 3.

15 FIG. 5 is a radial cross sectional view of the device shown in FIG. 3 and is taken along the line 5-5 of FIG. 3.

FIG. 6 is another radial cross sectional view of the device shown in FIG. 3 and is taken along the line 6-6 of FIG. 3.

20 FIG. 7 is a perspective isometric view of the distal end of an embodiment of the present invention showing an electrode configuration including multiple rings.

FIG. 8 is a distal end view of an embodiment of the invention.

FIG. 9 is a radial sectional view analogous to FIG. 6 of an embodiment of the invention.

FIG. 10 is a radial sectional view analogous to FIG. 5.

25 FIG. 11 is a radial sectional view analogous to FIG. 6.

FIG. 12 is a longitudinal sectional view of an embodiment of the invention, showing inflatable balloons.

FIGS. 12A, 12B, and 12C are radial cross sectional views of the embodiment of FIG. 12 and a related embodiment.

30 FIG. 13 is a perspective view of the distal end of an embodiments of the invention, depicting an alternative electrode positioning component.

FIG. 14 is a longitudinal sectional view an embodiment having expandable material.

FIGS. 14A and 14B are radial cross sectional view of the embodiment of FIG. 14.

5        FIGS. 15 and 15B are longitudinal sectional views of an embodiment of the invention having a deflectable tip.

FIG. 15A is a cross sectional view taken along the line 15A - 15A of FIG. 15.

FIG. 16 is a longitudinal view of an embodiment of the invention having steps to form a varying catheter diameter.

10        FIG. 16 is a longitudinal view of an embodiment related to FIG. 16, having forward firing electrodes.

FIG. 16B is a longitudinal view of an embodiment of the invention having a constantly varying diameter.

15        FIGS. 17 and 17A are longitudinal sectional views of an alternative embodiment of the invention having a plurality of slidable coaxial sleeves.

FIG. 18 is a longitudinal sectional view of an embodiment of the invention having spiral electrodes.

FIG. 18A is a cross sectional view taken along the line 18A - 18A of FIG. 18.

FIG. 18B is a view similar to FIG. 19A, after expansion.

20        FIG. 19 is a longitudinal view of an embodiment of the invention having flexible bristly electrodes.

FIG. 19A is a cross sectional view taken along the line 19A - 19A in FIG. 18.

FIG. 19B is a view of the embodiment having flexible electrodes in proximity to occlusive matter.

25        FIG. 19C is a view similar to FIG. 18B, in closer proximity to the occlusive matter.

FIG. 20 is a longitudinal view of an embodiment of the invention having a patterned foldable inflation balloon.

FIG. 20A is a cross sectional view taken along the line 20A - 20A of FIG. 20.

30        FIG. 20B is a view similar to FIG. 20, with the balloon deflated.

#### DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 shows the distal end 20 of one embodiment of a catheter 10 to remove an obstruction from a lumen within a patient, constructed according to the teachings of the present invention. FIG. 3 shows an overall view of the catheter 10. The catheter 10 is constructed, both by use of the appropriate size and materials, so that it may be inserted within and along the lumen of a blood vessel or other duct to a desired position. In the present context, the desired location is the obstructed site, such as, by way of example, an atherosclerotic plaque build-up in an artery. Usually, the obstruction is causing reduced fluid flow through the lumen.

Such a catheter 10 is elongate and defines the directions used herein as follows: "longitudinal" is along the length of the catheter axis; "radial" is transverse to the catheter axis, and "circumferential" is around the catheter axis.

One significant application of the device and method of the present invention is for ablation of atherosclerotic plaque located within coronary arteries. The device and method disclosed herein has, however, significant advantages over the prior art that may be useful in a number of minimally invasive procedures. The device of the present invention may be used, for example, in the following procedures: removal of fatty, fibrous, or calcific plaque from coronary, peripheral, renal or neurological arteries and veins; ablation of mucous from any mucous duct; the ablative treatment of fallopian tubes or other lumens of the genital-urinary tract; the removal of colon obstructions; the removal of blood clots or tissue build-up within the blood vessels of the brain or other organs; and the removal of undesirable intestinal tissue growth. In each of these procedures a catheter is manipulated to the desired location within the body via the lumen of a tubular body member, and energy is applied to the distal end of the catheter in order to ablate or resolve obstructive material.

Introduction of the catheter 10 to the appropriate site may be accomplished by use of a guide wire (not shown). The guide wire, with the appropriate bends and turns, is threaded through a lumen to the desired obstruction site. The catheter 10 may then be passed over the guide wire to the correct site.

The catheter 10 includes an elongate hollow tubular body 12. The body 12 is preferably flexible, and constructed of an electrically insulating material. Any of a number of polymeric or plastic materials may be employed for this purpose. Additionally, the catheter 10 is preferably constructed so that it is more flexible at the

distal end 20. This allows for the distal end 20 to be readily maneuverable, while the more rigid proximal sections allow for the easy insertion of the catheter 10 through a lumen. The variable rigidity may be accomplished by reducing the diameter of the catheter 10 material towards the distal end 20, by constructing the catheter of a more flexible material at the distal end, or by other methods.

The distal end 20 of the catheter 10 includes a plurality of electrodes 14. The electrodes 14 each constitute an electrosurgical electrode. The electrodes 14 may be constructed of any conductive material such as a metal or a metallic alloy commonly used to transmit RF current. For example, the electrodes 14 may be composed of stainless steel, tungsten, platinum, titanium, zirconium or any other refractory metal or alloy. The electrodes may also be formed of various conductive non-metallic materials, such as conductive plastics, rubbers, epoxies, and composite materials. While metal electrodes may achieve satisfactory results, these non-metal conductors may produce less trauma to an artery or other body lumen than metal electrodes, and thus cause fewer complications and improved patient recovery time. It may be desirable to use a traditional metallic electrode coated with a thin, softer non-metallic layer that is less irritating than metal and will not interfere with RF ablation. Also, a flexible printed circuit (PC) board may be used instead of a conductor, allowing for more sophisticated electrode control and positioning, as explained in more detail below.

The distal end 20 of the catheter 10 is preferably tapered. As shown in FIG. 1, the distal end 20 has a generally conical taper, although a catheter of other taper angles may be used depending on the application. Other shapes may also be used, such as a ballistic head as shown in FIG. 1A. The ballistic head is more rounded than a conical head, or, stated another way, has a varying degree of taper, with an increasing taper angle closer to the distal end. The use of a tapered head rather than a flat head allows the catheter 10 to be inserted more smoothly through a lumen to the obstruction site, and allows for the electrodes to be at a forward angle with respect to the catheter axis..

The interior 16 of the tubular body 12 of the catheter 10 has a generally constant diameter throughout the axial length of the catheter. Each of the electrodes 14 is separated from each other by the insulating material of the tubular body 12 (and optionally by another thermal insulator such as ceramics), and exists in part on the

circumference of the exterior surface of the tubular body 12 at the termination of the distal end 20, and in part on the cylindrical body of the catheter 10. Each electrode 14, therefore, consists of front 15 and radial 17 elements that are of unitary construction. The RF energy selectively delivered to each of the electrodes 14 will ablate obstructing material proximate to each of electrodes 14.

In a monopolar device of the present invention as is schematically shown in FIG. 2, the return path for the RF current introduced into the body tissue is through a patient plate 92. The patient plate 92 is a dispersion plate that is relatively large compared to the electrodes 14 and is attached to the body of the patient to establish contact with a significant amount of body surface area. The patient plate 92 is typically placed onto the hip, thigh, buttock or belly of the patient. Conduction from the patient to the patient plate 92 may be improved by applying conductive gel to the points of contact, as is known in the art.

In another embodiment, a single return electrode may be a large conductive ring 83. The ring 83 is on the catheter body 12 distal to electrodes 14, and has a surface area sufficiently larger than the surface area of the electrodes 14 so that the current density through the ring 83 will not affect tissue adjacent to the ring 83 (see FIG. 1B). As an example, generally good results may be obtained with a ring having four times the surface area of an electrode 14; an additional margin of safety may be obtained by having a surface area of ten times or more the surface area of an electrode 14. It should be understood that what has been described as ring 83 could have other shapes, and that more than one conductive return could be used, with similar results.

In either of these embodiments, the RF ablation may be controlled by selecting which electrodes 14 are active, i.e., which transmit RF current. With reference to FIG. 2A, the electrodes are individually labeled 14a, 14b, 14c, and 14d. Any combination of electrodes 14 may be selected as the active electrodes 14, and only tissue or obstructive material proximate these selected electrodes will receive RF energy in amounts high enough to ablate. For example, obstructive material 30 may be present only proximate electrode 14a, as shown in FIG. 2A. In that case, only electrode 14a will be activated. In another example, obstructive material may be present proximate electrodes 14a, 14b, and 14d (see FIG. 2B). In this case, energy will be supplied to these electrodes, with only electrode 14c in an open circuit. Obstructive material is

ablated from the active-electrodes 14a, 14b, and 14d, while any tissue proximate electrode 14c is unaffected.

The catheter 10 may be operative without including a specific return electrode. Instead, the current flow may simply be capacitatively coupled to a generator 98 by the conductance of the body of the patient and the surrounding environment. In such an embodiment, active electrodes 14 may be selectively operated as described above.

The catheter 10 may also be constructed as a "bipolar" RF source. In such an embodiment, a single return electrode may be included among the plurality of electrodes 14 at the distal end 20 of the catheter 10. RF ablation would then proceed from a selected electrode 14 to the single return electrode.

In another bipolar embodiment of the present invention, the power generator output 98 and return may be adapted so that any one of the plurality of electrodes 14 can serve as either the delivery or return electrode. With reference to FIG. 2C and the electrodes 14e, 14f, 14g, and 14h, any of the electrodes could be activated as the active electrode at a given time. For example, if the obstruction material adjacent electrode 14e is twice that adjacent to electrodes 14f and 14h, and with substantially no obstruction material proximate electrode 14g, electrode 14e would be selected as the active electrode and 14f and 14h would be simultaneously active as the return electrodes. Electrode 14g would be electrically open so as to take no part in the electrical circuit.

As all the electrodes 14 are preferably the same size, the current density through electrode 14e is twice the current density through electrodes 14f and 14h, so that the obstructive material adjacent electrode 14a would receive twice the RF energy as that adjacent electrodes 14f and 14h, and that adjacent electrode 14g would receive virtually no energy. In this embodiment, the directional specificity of ablation can be further controlled. The selection of the combination of active and return electrodes is dictated by the location of the obstructive material in relation to the position of the electrodes. In general, electrodes proximate to obstructive material will be either an active or return electrode, and electrodes not proximate to obstructive material will be open.

As shown schematically in FIG. 2, in any of the above embodiments, the catheter 10 is attached to and activated by an RF power supply 98. Each electrode 14

is coupled to the power supply via a wire conductor 40 that runs the entire length of the tubular body 12. Each wire 40 may be electrically insulated.

Referring to FIG. 3, the proximal end 50 of the catheter 10 preferably has a "Y" shaped portion that has a straight through passage 53 and a branch passage 54.

5 The interior 16 of the tubular body 12 may be accessed from either the straight through 53 or the branch 54 passage. The wire conductors 40 are coupled to the generator 98, and prior to insertion into the catheter 10 via the branch passage 54 may be bundled together to form a single transmission wire 42, as shown in FIG. 9, or may remain separated.

10 The RF generator 98 includes an electrode switching device 96 such that the output of the generator may be selectively applied to one of the wire conductors 40, and therefore to one of the electrodes 14. This allows the selection of the combination of electrodes that participate in the RF ablation, as discussed above. Of course, the switching device need not be physically included within the generator 98, but may be  
15 any suitable component of the overall circuit. The RF system further includes means for power modulation 93 and waveform modulation 95 so that the desired RF current may be applied.

The transmission wire 42 or wire conductors 40 enter the catheter 10 via the branch passage 54 at the proximal end 50 of the catheter 10. In FIG. 9, which shows  
20 an embodiment of the invention utilizing a single transmission wire 42, each of the wire conductors contained within the transmission wire 42 are electronically insulated from each other. In addition, the exterior surface of the transmission wire 42 is coated with an insulating material. In a preferred embodiment of the invention, each of the wire  
25 conductors 40 will be separately insulated, and will proceed separately through the catheter as seen in FIGS. 3, 5 and 6. Alternatively, a multiplexer may allow for fewer conductors 40 to run through the catheter than the number of electrodes 14.

FIG. 6 shows a radial sectional view of the catheter 10 at a point between its distal 20 and proximal 50 ends. The wire conductors 40 are located within the interior  
30 cavity 16 of the tubular body 12. The wire conductors 40 are designed so that they will not take up significant amounts of the interior volume of the tubular body 12 and so that the individual wires will not cross-talk with each other, nor will they affect the electrode positioning elements, which are described below. Further, space is allowed

for the passage of medicinal or other fluids through cavity 16 and the distal end 20 of the catheter for application to the obstruction site, and to encompass the guide wire that is preferably used to properly place the catheter 10.

As can be seen in FIG. 3, the wire conductors 40 run nearly the full length of the tubular body 12. At a point 45 just near the distal end 20 of the catheter 10, the individual wire conductors 40 are coupled to the electrodes 14. FIG. 5 is a radial cross sectional view of the catheter 10 at the point 45 where the wire conductors 40 each connect to a corresponding electrode 14.

FIGS. 10 and 11 show an additional embodiment of the invention wherein the wire conductors 40 are separately contained within separate lumens within the tubular body of the catheter 10.

The catheter 10 includes means for physically positioning the electrodes 14 within a lumen, so that the active electrodes 14 will be either physically touching or within an acceptable distance from obstruction material before RF current is applied. The positioning of the electrodes 14 in the direction of the length of the catheter 10 may be accomplished by further inserting or retracting the catheter 10 through the lumen. Further positioning may be done radially away from the axis of the catheter 10, so that the active electrodes 14 are positioned against the obstruction site. While an acceptable distance may depend upon the specific body lumen and obstruction material to be resolved, optimal results may generally be achieved when an electrode 14 is activated within .5 mm of an obstruction site.

With reference to FIG. 12, one embodiment of the present invention uses one or more inflatable balloons 30 spaced about the tubular body 12 beneath the electrodes 14. The electrodes 14 are also located on an exterior surface of the inflatable balloons 30. The catheter 10 also includes means for selectively inflating the balloon 30 to radially position the electrodes 14. The inflatable balloon 30 is formed as an expanded portion of a flexible lumen 32 (such as latex) within or on the tubular body 12. The lumen 30 may be formed of latex or a similar compliant material. The balloon 30 is capable of an amount of inflation such that the electrodes 14 may be placed into contact with an obstruction site in a lumen by inflating the balloons 30. The physical dimensions will, of course, vary with the specific application.

Lumen 32 defines both an inflation lumen or conduit and the inflatable balloon 30. The balloon 30 is the terminated end of the lumen 32, and is not bound by the catheter body 12 so that it can expand. The portion of the lumen 32 other than the balloon 30 is prevented from significant expansion by the catheter body 12 or a similar member. The initial size of lumen 32 is not critical so long as it may be manipulated to achieve the desired radial positioning of the electrodes 14.

The expansion of the balloon 30 may be achieved by a variety of inflation methods, such as injecting a pressurized gas such as carbon dioxide into the lumen 32, or injecting a liquid such as sterilized saline solution or contrast media. A spacer block or other means may be inserted to limit the expansion of lumen 32 if desired.

A radial cross section is shown in FIG. 12A with the balloon 30 deflated, and is shown in FIG. 12B with the balloon inflated. In the illustrated embodiment, three electrodes 14 are shown, although more or fewer electrodes 14 could be used if greater or lesser circumferential selectivity is desired. If the electrodes 14 are not formed of an expandable material, the spacing between the electrodes 14 (denoted "I") will increase as the balloon 30 is expanded. Depending upon the application, this may not be a detriment, as the electrodes 14 may cover a sufficient area to effectively ablate an obstruction. An alternative embodiment shown in FIG. 14C has expandable electrodes 14'. The material of the expandable electrodes 14' may be of any conductive material that has an elasticity comparable to the elasticity of the balloon 30 material, such as conductive plastic. Or, the expandable electrode 14' may be thin metal layer deposited on a more elastic material, so that the thin metal layer can effectively expand with the more elastic material. As seen in FIG. 14C, the spacing I between expandable electrodes 14' when inflated is approximately the same as the spacing between the electrodes 14 when deflated. The use of expandable electrodes 14 allows the catheter surface to be nearly completely covered by the electrodes 14 whether the balloon is deflated or inflated.

Additional embodiments of the invention have electrodes that can be radially directed through means other than the inflatable balloon 30. One such embodiment is described in connection with the longitudinal section of FIG. 14 and the corresponding radial cross sections of FIGS. 14A and 14B. The catheter body 12 surrounded by a ring of expandable material 160. The ring 160 is surrounded by a sleeve 162.

Electrodes 14 are positioned on the sleeve 162. Three electrodes 14 are shown for purposes of illustration; more or fewer may be used.

Expanding the material 160 displaces the sleeve 162 and hence the electrode 14 radially away from the axis of the catheter body 12, as shown in FIG. 14B. The effect is similar to the expanding balloon 30, in that an electrode can be selectively positioned by expanding an underlying component. In the present case, the expandable material 162 can be expanded in various ways depending upon the material choice. The material 162 can be kynar or a similar material that elongates and expands upon an application of electrical field or voltage. Suitable means for supplying electricity (such as through the transmission wire 42 or other wiring engaged with a suitable power source) are engaged with the expandable material 160. The expandable material 160 retracts to its original size and shape upon the elimination of the electricity. By applying and eliminating electricity, the electrodes 14 can be radially positioned as desired, subject to the physical limitations of the expansion of the material.

A closely related embodiment uses nitinol or a similar material that expands upon heating as the expanding material 162. While most metals and many other materials expand somewhat when heated, nitinol has a relatively high coefficient of thermal expansion so that it is particularly useful for expanding an electrode 14 a therapeutically significant distance. The nitinol 162 can be heated by an application of electricity, which can be accomplished by the transmission wire 42 or other wires as discussed above. The embodiments using an expanding material 162 may be advantageous compared to the balloon embodiment in that it may be simpler to supply current to the distal end of catheter than inflation media such as saline solution. However, balloons 30 may accomplish greater physical movement of an electrode.

Referring to FIG. 13, in another embodiment of the invention the catheter is deflected by a propulsion jet 150. Fluid such as sterile saline solution 152 is discharged from the propulsion jet 150, thereby causing the catheter 10 to move in the opposite direction. Of course, more than one propulsion jet 150 may be used, and, if the jets are disposed around the body of the catheter, activating the proper jet may position catheter in virtually any radial direction.

Another embodiment of the invention is illustrated in the longitudinal view of FIG. 15 and the corresponding radial view of FIG. 15A. A catheter distal tip 20 has at

least one and preferably a plurality (such as four that are illustrated) of longitudinally adjustable strips 170. The strips 170 are mechanically engaged with the catheter body 12, so that movement of the strips 170 urges corresponding movement in the catheter body 12. The strips 170 may be of a thermally or electrically expandable material as disclosed above in connection with the embodiments of FIGS. 14A-14C. Thus the strips 170 could be thermally expandable nitinol, or electrically expandable material such as kynar, bimorphic crystal, a bimetal strip, or other materials. Appropriate current can be supplied by the transmission wire 42 or similar current source. As another embodiment, the strips 170 can be longitudinally positioned by movement from the proximal end of the catheter, that is, the strips 170 can be physically inserted or retracted along the length of the catheter.

The strips 170 are all offset from the axis of the tube 12, so that asymmetrically extending or retracting the strips 170 deflects the catheter distal end 20 from the catheter axis. By extending (or retracting) one of the strips 170, the catheter distal end 20 can be deflected away from (or towards) that strip 170 in relation to the catheter axis. That is, the catheter tip 20 bends. By extending or retracting combinations of the strips 170, the distal end 20 can be deflected in a desired direction. Deflecting the distal end also deflects the electrode(s) 14 thereon, so that the electrodes can be positioned as desired.

Yet another embodiment of the invention is disclosed in connection with the longitudinal elevation view of FIG. 16. The distal end of the catheter has a varying diameter along its length, and a plurality of electrodes 14 positioned along the varying diameters. In the embodiment of FIG. 16, the distal end 20 has three stepped sections 180, 182, and 184. The most proximal section 180 has the greatest diameter, and supports a electrode 14. The next section 182 has a somewhat lesser diameter, and supports another electrode 14. The third section 180 has a lesser diameter than the section 182, and also supports an electrode 14. While three sections are illustrated, more or fewer sections can be provided so that a catheter has a desired number of electrodes at differing radial distances from the catheter axis.

The three sections 180, 182, and 184 allow for effectively ablating material within a lumen regardless of the material's position. For example, three obstructive material deposits M1, M2, and M3 are shown within a lumen 100. The material M3

may project furthest from the lumen 100 and be ablated by the electrode 14 of section 184. The material M1 may project least and be ablated by the electrode 14 of section 180. The material M2 is intermediate and may be ablated by the electrode 14 of section 182. It should be understood that the material M1, M2, and M3 is only for the purpose of illustrating the concept of using electrodes of varying radial positions to ablate material of different positions within a lumen, and not to illustrate any specific obstruction within a body.

A modified embodiment is illustrated in FIG. 16A, which is similar to FIG. 16. The electrodes 14 are positioned so that they have a component that is forward firing, that is, electrically operative in the direction of the catheter axis. The embodiment may allow for easier catheter penetration through an obstructed lumen, in that material obstructing catheter 10 motion can be ablated.

Another modified embodiment is illustrated in FIG. 16B. Again, electrodes 14 are disposed on the distal tip 20 of a catheter, the electrodes being disposed at a varying diameter from the catheter axis. In this embodiment, the catheter distal tip is not stepped as in FIG. 16; instead it has a constantly decreasing diameter. In operation, the electrodes 14 extending further radially away from the catheter axis can be activated to ablate material closer to a lumen wall 100, while electrodes 14 extending less far can ablate material further from the lumen wall 100. It should also be appreciated that the curvature of the distal tip 20 in FIG. 16B could be non-constant (described as "ballistic" above), and that other configurations can be used to position a plurality of electrodes at varying radial positions.

Still another embodiment of the invention is illustrated in connection with the longitudinal sectional view of FIG. 17. In brief, several coaxial sleeves are slidably aligned with one another and each sleeve supports an electrode. Presenting a different sleeve to an ablation site allows an electrode at a desired radial position to be activated as necessary. An innermost member 210 supports a visualization means 212 such as an ultrasound transducer, fiber optic or other optical sensor, or otherwise. The member 210 is surrounded by a first sleeve 214, the sleeve 214 having one or more electrodes 14 on a distal end. Sleeve 214 is surrounded by a second coaxial sleeve 216 having one or more electrodes 14 on a distal end. Likewise, sleeve 216 is surrounded by a third coaxial sleeve 218 having one or more electrodes 14 on a distal end.

Each of the sleeves 214, 216, and 218 are slidable with respect to each other and the member 210. The sleeves may be slid by a control at a proximal catheter end external body, such as by pulling or pushing on a proximal sleeve portion. In connection with the information provided by ultrasound transducer 210, the operator  
5 can advance the appropriate sleeve 214, 216, or 218 to an ablation site. The appropriate sleeve is one which will have approximately the same position as the material to be ablated at the site. In operation, the member 210 is generally first advanced distally through a lumen until an obstruction is detected, and the appropriately sized sleeve (together with any internal sleeves) will then be advanced to  
10 the site. The obstruction material will then be ablated by activating the electrode 14 on the appropriately sized sleeve; the member 210 is again advanced, and the process is repeated. While three sleeves are illustrated, it should be appreciated that more or fewer could be used in a similar manner.

The use of the sleeved catheter is illustration in FIG. 17A. The visualization means 212 has detected obstruction material M within a lumen 100, and the sleeve 216  
15 has been advanced to the site of the material M, it being the largest sleeve that will fit within the lumen 100 as obstructed by the material M. The sleeve 214 may be simultaneously advanced. The electrode 14 on sleeve 216 will be activated to ablate the material M, whereafter the sleeve 218 can be advanced so that the sleeves are  
20 advanced generally in unison.

Another embodiment of the invention is described in connection with the longitudinal view of FIG. 18 and the radial cross sections of FIGS. 18A and 18B. The catheter 10 has an expandable balloon section 110 on a distal end. (The balloon could be replaced with another expandable section according to any of the above described  
25 embodiments). The balloon section 110 is partially covered by an expandable sleeve(s) 120. The sleeves 120 support curved electrodes 130. As shown in FIG. 18A, four spiral electrodes 130a-130d are included, although alternative embodiments could include more or fewer electrodes. The spiral electrodes 130 curve around the catheter 10 axis, and can be selectively activated to ablate occlusive material. Power is supplied  
30 to the electrodes 130 as described in any of the above embodiments. Each of the electrodes are attached at one end to the catheter, and spiral radially away from and

around the catheter 10 body. The spiral electrodes 130 partially overlap one another so that a portion of the catheter 10 is completely surrounded by the spiral electrodes.

The catheter 10 is shown with the balloon section 100 expanded in FIG. 18B.

The balloon can be expanded as described in other embodiments, and the balloon section 110 expands the sleeve 120 and the spiral electrodes 130 away from the catheter axis. The spiral electrodes 130 overlap each other to a lesser extent when the balloon is expanded. However, the spiral electrodes 130 are configured such that they still at least partially overlap one another. Thus, a portion of the catheter 10 is still completely surrounded by the spiral electrodes 130, and it can be appreciated that the spiral electrodes allow for the complete circumferential coverage of the electrodes over a range of catheter inflation.

Another embodiment of the invention is shown in FIGS. 19, 19A, 19B, and 19C. A distal end of the catheter 10 supports a plurality of thin, flexible bristle electrodes 140. In the radial cross section of FIG. 19A, four rows of radially extending bristle electrodes 140a-140d are shown, although more or fewer rows could be used in other embodiments. Each of the rows of bristle electrodes 140 can be selectively activated, as described in connection with other embodiments.

A slidable insulating sheath 142 covers the catheter 10 and the bristle electrodes 140 as shown in FIG. 19. The bristle electrodes are sufficiently flexible so that contact with the sheath 142 biases the bristles to lay generally along the catheter 10 axis. In this position, the catheter 10 is inserted until the bristle electrodes 140 are, but for the sheath 142, adjacent occlusive material such as material 30 in FIG. 19. The sheath 142 is then proximally withdrawn, as in FIG. 19B. The bristles assume their unbiased position of extending radially away from the catheter 10, and directly contact the occlusive material 30. RF current is applied to electrodes 140 and the material 30 is ablated. The sheath is then advanced distally to cover the bristle electrodes 140, and the catheter is withdrawn.

An advantage of the bristle embodiment is that the bristle electrodes 140 can contact occlusive material 30 at a range of distances from the catheter 10. As shown in FIG. 19C, occlusive material may be closer to the catheter 10 than the length of one bristle electrode 140. In such case, the electrode 140 flexes towards the catheter (similarly to when the sheath 142 covers the electrodes). As the material 30 is ablated,

the electrode 40 will unflex and maintain contact with the remaining material 30, until the electrode is fully extended (as shown in FIG. 19B).

Another embodiment of the invention is described in connection with the longitudinal view of FIG. 20 and the radial cross sectional views of FIG. 20A and 20B.

5 A catheter has inner tubing 220 (corresponding to catheter body 12 in previously described embodiments) surrounded by an inflatable balloon 230. As shown in FIGS. 20 and 20A, the inflated balloon 230 has a circular cross section, similar to the embodiment described in connection with FIG. 12. The balloon 230 supports a plurality of electrodes 14. The electrodes 14 can be activated singularly or in any  
10 combination, and in either monopolar or bipolar systems, as described elsewhere herein. At least some of the electrodes 14 are placed adjacent obstructive material, and activation of the electrodes 14 selectively ablates a portion of the material. As material is ablated, the balloon 230 is further expanded to continue contacting the remaining material.

15 As shown in FIG. 20B, when the balloon 230 is deflated, it is formed of four separated arm sections 232. Each arm 232 has a section 234 that extends radially from the inner tubing 220 and curved section 236 that extends circumferentially from the radial section 234.

In the deflated state, the curved section 236 extends nearly at approximately  
20 right angles from the radial extending section. As the balloon 230 expands, the curved section 236 gradually uncurls with respect to the inner tubing 220. Continued inflation eventually inflates and uncurls the curved sections 236 (along with the radial sections 234) until they interconnect and form the circular shape as in FIG. 20A. The shape and expansion pattern can be achieved by selection of material of suitable composition  
25 and configuration, and it can be readily understood that continued inflation of a shaped object causes the object to form a more circular shape as inflation pressure uniformly distends the object.

The above embodiment is advantageous in that at least some of the electrodes  
30 14 will maintain contact with material as the material is partially ablated, and in that the balloon 230 forms a compact shape when deflated. It can be readily understood that either more or fewer than four arm sections 232 can be included, and that the curved sections 236 can curve around the inner tubing 220 at other than a right angle in the

deflated state. The essential feature of the above embodiment is that a number of arms uncurl from the tubing as they inflate, and that the arms at least partially merge into one another upon inflation.

Other methods may also be used to position the catheter electrodes 14. As  
5 examples, electromagnets could be placed radially around the catheter, and selectively applying the proper current would repel the magnets from each other to selectively distend the catheter. Of course, many other positioning methods could also be used. While the above examples are believed to be an important advance and the art and provide useful devices and methods, they are not an exhaustive rendition of all  
10 methods that could be used to position a catheter within a lumen that may fall within the scope of the present invention.

The method of obstruction resolution with the catheter 10 may be improved by the use of some means for visualizing the interior of the lumen and the obstruction site. This can be accomplished by placing ultrasound transducers 85, as shown generally in  
15 FIG. 7 at the catheter distal end 20 under the electrodes 14. The physical interrelationship between the electrodes 14 and the transducers 85 may take a number of forms. Placing the transducers 85 underneath the electrodes 14 as shown allows the position of the electrodes 14 to be exactly correlated with the position of the transducers 85. However, the transducers may be placed adjacent to the electrodes 14,  
20 to insure that the electrodes do not interfere with the transducers 85. Also, the relative number of transducers 14 and electrodes may be varied. For instance, there could be a one-to-one correspondence between the number of electrodes and the number of transducers 85. Alternatively, either more or fewer transducers 85 could be used than the number of electrodes 14. The transducers 85 send and receive ultrasonic signals  
25 which are processed using ultrasonic processing means 101 and these results may be displayed on video terminals or other ultrasound monitors 102 as shown in FIG. 2.

Other visualization techniques may be used either instead of or in conjunction with ultrasound. A fiber optic cable may inserted through the catheter, and may directly transmit a visible picture of the lumen interior. Other visualization techniques  
30 may include, but would not be limited to, the following: the introduction of radionuclear dyes that allow for radiographic visualization at the obstruction site or in the lumen generally; high resolution biplane angiography; or the use of a photodynamic

material which fluoresces in smooth muscle tissue under light excitation of a specific wavelength.

Whatever means are used to determine the situs of the obstruction, the initial step is generally the placement of at least one of the active electrodes 14 adjacent to the proposed ablation site. As described above, the appropriate positioning may be accomplished with the aid of a guide wire. Guide wires are constructed so that the wire will be introduced into the lumen and threaded to the desired position. The placement of catheters is a well known and often performed procedure in connection with balloon angioplasty and other such surgical procedures. In the present invention the placement is critical not only with respect to the extension of the catheter distal end through an artery, but also with respect to the circumferential orientation of the catheter since the RF energy is applied differentially along the circumference to correspond to differential obstruction build-up.

When using a guide wire to help manipulate the distal end 20 of the catheter 10 to the appropriate location, the end of the guide wire exiting the patient may be used to guide the catheter 10 by use of the hollow interior 16 of the tubular body 12. The guide wire can be removed from the interior of the catheter 10 when resolution is to begin, or may be maintained in place if required by the attending physician.

The interior cavity 16 of the catheter 10 may also be used to introduce fluids to the site of plaque destruction. For example, as an aid to visualization it may be desirable to flush the obstruction site. The introduction of dyes to aid the visualization process may also be accomplished via the interior cavity 16. Aside from improving visualization, medicinal liquids may be introduced through the cavity 16.

With reference to FIG. 2, the electrodes 14 projecting at the face of the distal end 20 of the catheter 10 may be shaped so that ablation may occur in both forward (distal) and radial directions. It is therefore possible to resolve obstructions that have built up to such an extent that the catheter 10 is physically prevented from proceeding through a lumen. RF ablation from the front portions 15 of the electrodes 14 will allow some forward directed ablation, as the current will flow from all of the exterior electrode 14 surface. Generally, the exterior diameter of the tubular body 12 is sized such that it is substantially smaller than the interior diameter of lumens in which it will be used. However, unless the obstruction buildup has progressed extremely far, it

should be possible to place the distal end 20 of the catheter 10 in a position so that the plaque obstruction to be resolved will be generally planar to the side elements 17 of the electrode 14 selected to ablate the plaque.

Once the distal end 20 of the catheter 10 is properly placed, the operator must  
5 determine by consultation with the visualization technique utilized which surfaces of the artery or vessel require ablation. Rather than random sparking delivered from the RF electrodes 14, it is possible to selectively ablate only the obstructed surfaces, so that undamaged or minimally damaged tissue surfaces may be left unharmed.

In the embodiment of the catheter 10 shown in FIGS. 7 and 8, the electrodes  
10 14 consist of a plurality of split rings 80 spaced along the exterior surface of the distal end 20 of the catheter 10. Each of the split rings 80 are separated from each other by an amount of the insulating material that comprises the bulk of the catheter 10. FIGS. 7 and 8 show a catheter including two groups of split rings 80. However, as many split rings 80 as desired can be included. The use of multiple groups of rings 80 allows  
15 for more ablation control than would a single electrode. By activating different rings 80, ablation can be controlled in the axial direction of the catheter 10 as well as in the circumferential direction.

Each ring 80 is "split" into a plurality of separate electrodes by equally spaced portions of insulating material. The embodiment of FIGS. 7 and 8 show the rings 80  
20 divided into four sections. However, the rings could be divided into more or fewer sections. For example, the embodiments illustrated in FIG. 14 is shown having three circumferential sections. Using more ring divisions allows for greater selectivity in determining the areas of ablation, as the smaller radius of the electrodes 14 will ablate a correspondingly smaller area of the surrounding lumen.

The embodiment of the invention shown in FIGS. 7 and 8, and the embodiment  
25 shown in FIG. 1, may be adapted to serve as either monopolar or bipolar electrosurgical catheters. The embodiment shown in FIG. 7 has a total of twelve electrodes. When adapted to perform as a bipolar device in which each of the twelve electrodes may be selected to function as a transmit or receive electrode, the positional  
30 specificity for ablation at the site of plaque build-up is greatly enhanced. It is again emphasized that the particular embodiments described and shown in the drawings are representative only, and that many combinations could be effectively employed. For

instance, the rings 80 could be undivided (although this would not allow for circumferential selective ablating), or could contain any number of divisions. Any number of rings 80 may be used. Also, it is not necessary to group the electrodes into rings at all. The electrodes could be disposed about the body of the catheter in any pattern whatsoever. However, the use of regular groupings, such as the depicted series of rings 80, insures that at least one of the electrodes 14 will be relatively close to any given obstruction site.

It is contemplated that the various improvements and configurations described above can be combined with one another in any configuration to provide a useful device and method. The description given and examples presented are for purposes of illustration and are not meant to limit the claims and legal equivalents set forth below.

CLAIMS

What is claimed is:

1. A radio frequency ablation device for resolving an occlusive deposit in a lumen having an axis, comprising:

5                   (a)     an elongate flexible hollow tube having a distal end, a proximal end, and a diameter smaller than the lumen into which said device is being inserted;

                  (b)     a plurality of electrodes circumferentially disposed about said tube proximate the distal end;

                  (c)     selection means in electrical communication with the electrodes  
10     for selectively supplying a radio frequency electrical current to at least one of said electrodes whereby said at least one electrode becomes a transmitting electrode to ablate said occlusive deposit; and

                  (d)     means for radially positioning and retracting said electrodes with respect to said lumen axis.

15               2. The device of claim 1, further comprising an inflatable lumen proximate the distal end of the elongate tube, and wherein the means for radially positioning said electrodes includes said inflatable lumen.

                  3. The device of claim 2, wherein said inflatable lumen is disposed about said flexible hollow tube beneath said electrodes.

20               4. The device of claim 2, wherein said plurality of electrodes are circumferentially spaced about said tube.

                  5. The device of claim 4, wherein said electrodes are expandable, so that said electrodes have a surface area that increases upon inflation of said inflatable lumen.

25               6. The device of claim 1, further comprising a propulsion jet situated on the elongate tube and fluid expellable from said propulsion jet, and wherein the means for positioning the electrodes includes expelling fluid from said propulsion jet.

                  7. The device of claim 1, further comprising expandable material disposed about a circumference of said elongate tube, and wherein the means for positioning the electrodes includes expanding said expandable material.

30               8. The device of claim 7, wherein said expandable material is expandable upon an application of electricity.

9. The device of claim 8, wherein said expandable material is selected from the group consisting of kynar films, birmorphic crystals, or bimetalic strips.

10. The device of claim 7, wherein said expandable material is expandable upon heating.

5 11. The device of claim 10, wherein said expandable material is nitinol.

12. The device of claim 11, further comprising an expandable sleeve situated between said expandable material and said electrodes.

13. The device of claim 1, further comprising at least one strip of material engaged with the tube distal end, said strip being extendable or retractable along a length of said tube, said strip being offset from a tube axis, whereby extending or retracting said strip deflects said distal end from said tube axis.

14. The device of claim 13, wherein said strip is extendable or retractable upon an application of electric current.

15 15. The device of claim 16, wherein said strip is selected from the group consisting of kynar films, birmorphic crystals, or bimetalic strips

16. The device of claim 13, wherein said strip is extendable or retractable upon pushing or pulling said strip from said proximal end.

17. The device of claim 1, wherein said radio frequency current flows through a patient plate attached to a portion of the subject remote from the location of the occlusive deposit.

18. The device of claim 1, wherein said radio frequency current flows through a return electrode mounted on said elongate tube.

19. The device of claim 1, wherein said selection means further includes means for selecting at least one of said electrodes to act as a return electrode.

20. The device of claim 1, wherein said selection means select an electrode to act as a transmitting electrode at a first time and to select the same electrode to act as a return electrode at a second time different from said first time.

21. The device of claim 1, wherein at least some of the electrodes are disposed around the tube in a segmented ring.

22. The device of claim 21, further comprising at least two segmented rings.

23. The device of claim 1, further comprising means for remotely visualizing the position of the electrodes within the lumen.

24. The device of claim 1, wherein the means for remotely visualizing the position of the electrodes include ultrasound transducers mounted on the catheter.

25. The device of claim 24, wherein the means for remotely visualizing the position of the electrodes include a fiber optic wire, at least part of the fiber optic wire being within the catheter, and at least part of the fiber optic wire extending distal to the catheter.

26. The device of claim 1, wherein at least one of the plurality of electrodes are at least partially non-metallic.

27. The device of claim 1, wherein the tube has a radially expandable section; and wherein at least some of the plurality of electrodes are positioned on the radially expandable section and are spiral shaped and spiral away from and partially around the lumen axis, the spiral shaped electrodes partially overlapping one another so that a portion of the hollow tube is completely surrounded by the spiral shaped electrodes over a range of radial expansion.

28. The device of claim 1, wherein at least some of the plurality of electrodes are thin flexible electrodes that extend radially away from the tube in an unbiased state; and further comprising an insulating sheath that partially covers the tube and is slidable in relation to the same;

wherein sliding the sheath in a first direction uncovers the flexible electrodes so that the flexible electrodes are capable of ablating the occlusive deposit and sliding the sheath in a second direction opposite the first direction covers the electrodes so that they shielded from ablating.

29. The device of claim 28, wherein the flexible electrodes are sufficiently flexible so that they can partially flex against the occlusive material and unflex and maintain contact with the occlusive material as the occlusive material is ablated.

30. A radio frequency ablation device for removing an occlusive deposit in a lumen, comprising:

an elongate flexible hollow tube defining an axis therethrough and having a distal end, a proximal end, and a diameter smaller than the lumen into which said device is being inserted;

said tube having a varying diameter along its length, whereby a plurality of tube sections each having a different diameter is provided; and

each of said tube sections has at least one electrode, whereby the tube has a plurality of electrodes at different radial positions with respect to said tube axis.

31. The device of claim 30, whereby said plurality of tube sections result from a series of steps formed within said tube.

5 32. The device of claim 30, whereby said electrodes are positioned on said steps so that each electrode has a portion facing longitudinally with respect to said tube axis and a portion facing radially away from said tube axis.

33. A radio frequency ablation device for resolving an occlusive deposit in a lumen, comprising:

10 a plurality of coaxial sleeves being slidable with respect to one another, each of said sleeves having a distal end and an electrode on said distal end;

said sleeves being insertable within the lumen, whereby the deposit can be ablated by activating at least one of said electrodes.

15 34. The device of claim 33, further comprising means for visualizing said lumen.

35. The device of claim 1, further comprising an expandable balloon, the plurality of electrodes being at least partially disposed about said balloon; the balloon having a deflated state and being formed of a plurality of arm sections in its deflated state, each arm section having a radially extending section and a curved section  
20 extending circumferentially from the radially extending section; whereby inflating the balloon at least partially uncurls each curved section, and each arm section approaches another arm section so that the balloon assumes a more circular cross section.

36. The device of claim 35, comprising four arm sections, wherein each curved section forms approximately a right angle with respect to one of the radially extending  
25 sections when the balloon is deflated.

37. A method for resolving an occlusive deposit in a tubular passage of a tissue of a subject comprising:

(a) engaging said subject with an electrosurgical device comprising an elongated flexible hollow tube having a distal end, a proximal end, and a diameter  
30 smaller than the tubular passage into which said device is being inserted; a plurality of electrodes proximate said distal end of the tube, the electrodes being spaced about the tube;

(b) positioning said electrosurgical device within said tubular passage until at least one of said electrodes are proximal to said occlusive deposit, this step including radially positioning said device with respect to the axis of the tubular passage.

1/7

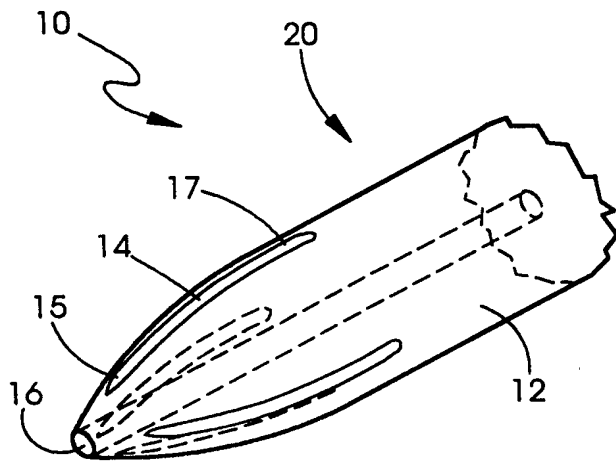


FIG. 1

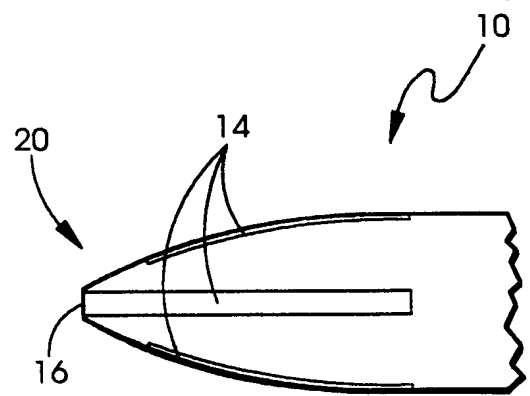


FIG. 1A

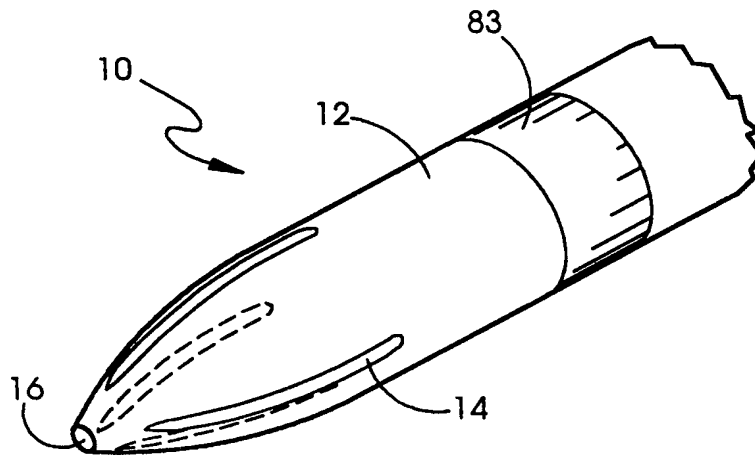


FIG. 1B

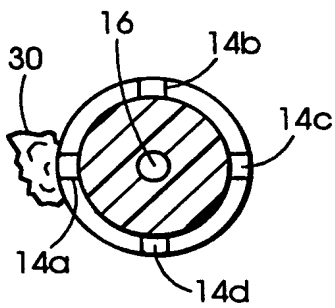


FIG. 2A

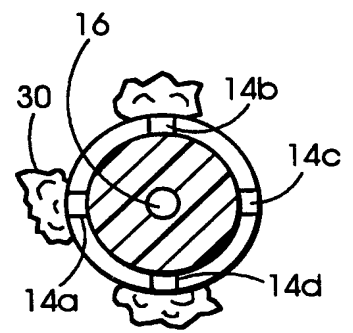


FIG. 2B

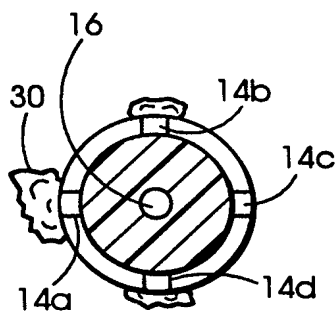


FIG. 2C

2/7

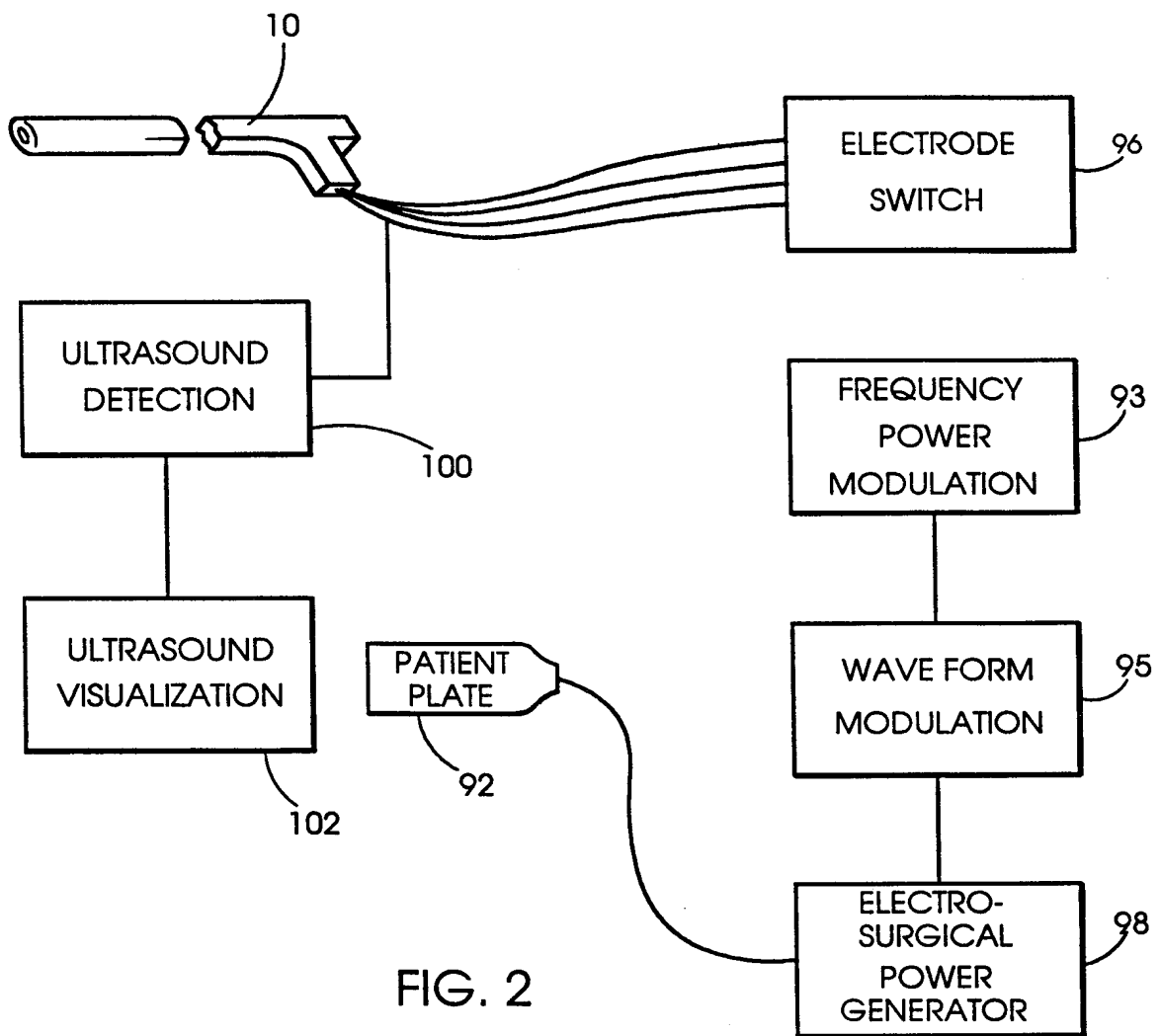


FIG. 2

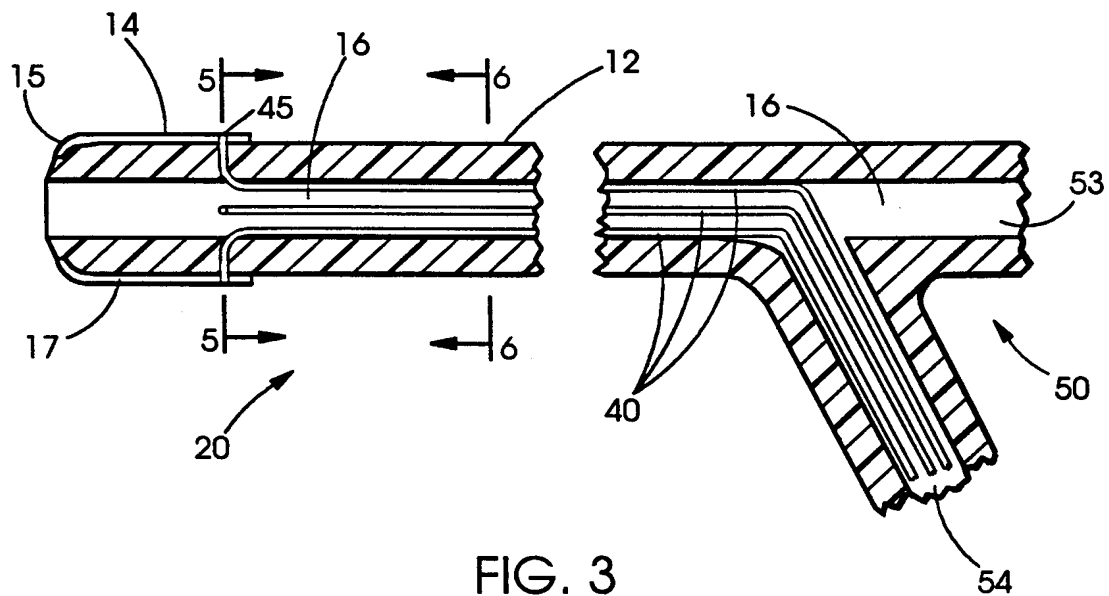


FIG. 3

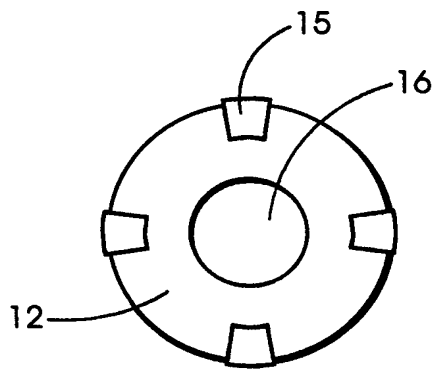


FIG. 4

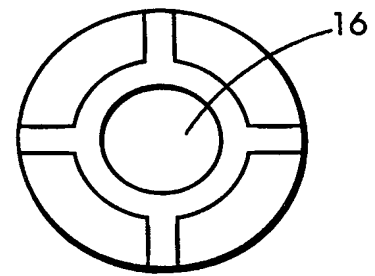


FIG. 8

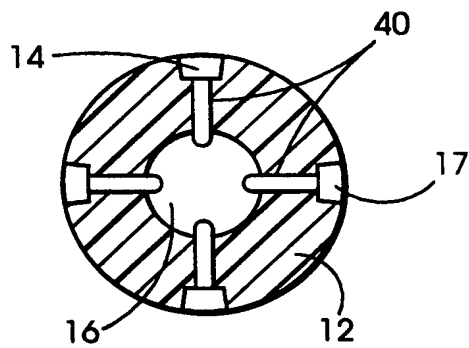


FIG. 5

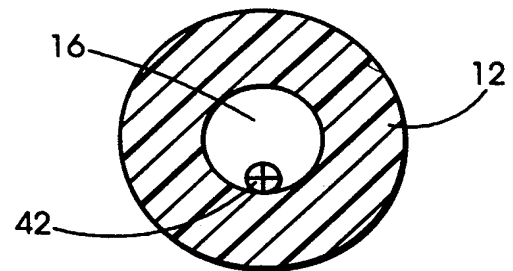


FIG. 9

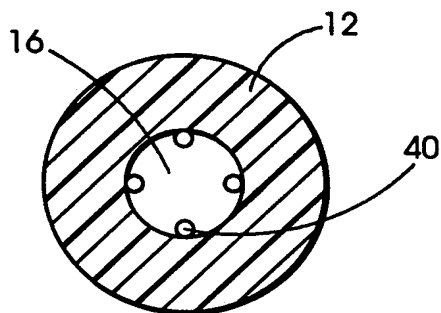


FIG. 6

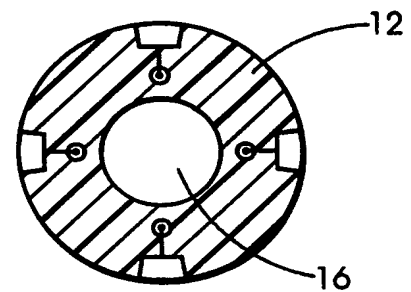


FIG. 10

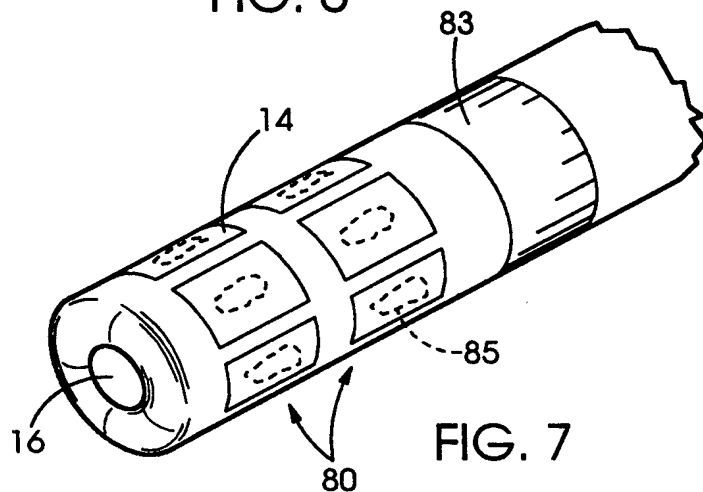


FIG. 7

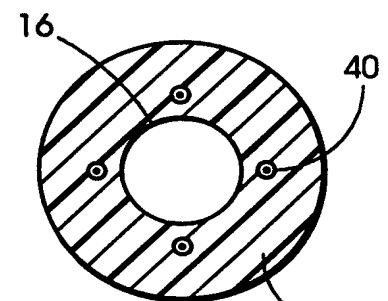


FIG. 11

4/7

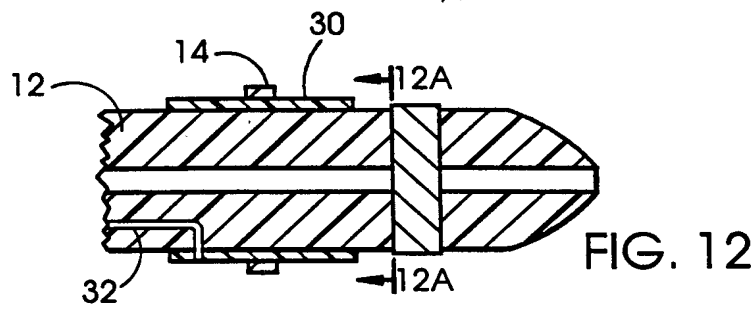


FIG. 12

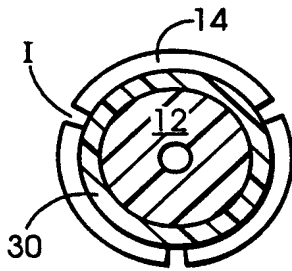


FIG. 12A

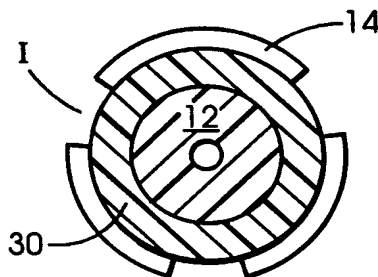


FIG. 12B

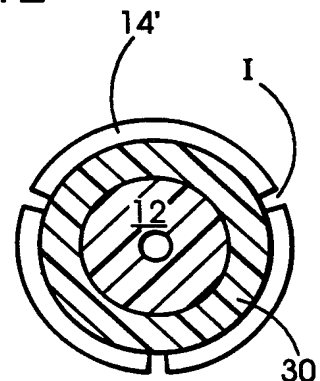


FIG. 12C

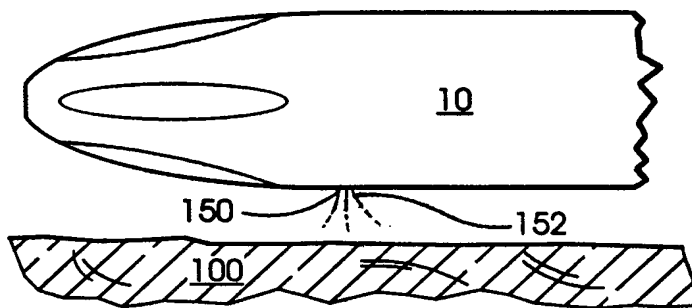


FIG. 13

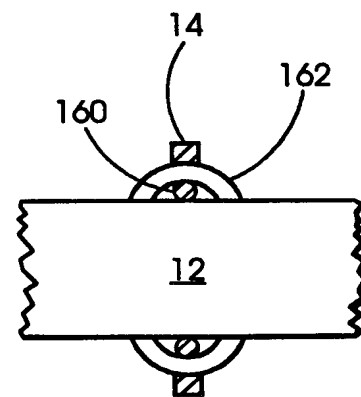


FIG. 14

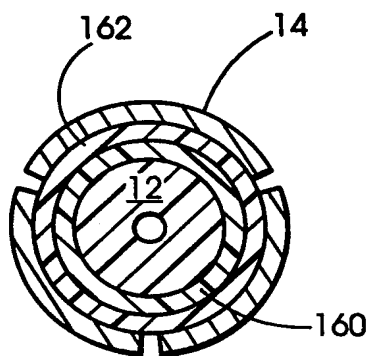


FIG. 14A

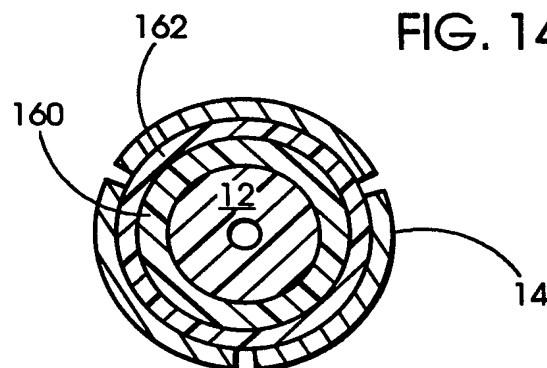


FIG. 14B

5/7

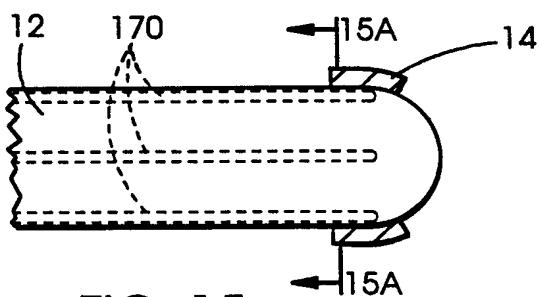


FIG. 15

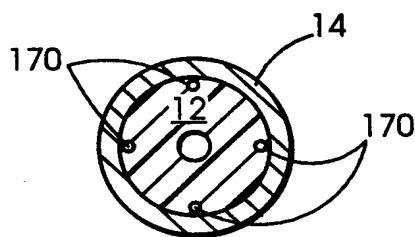


FIG. 15A

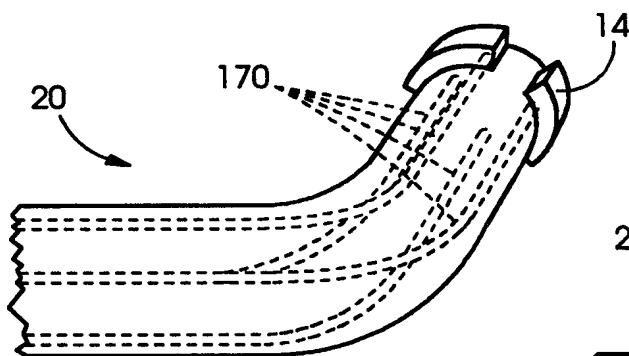


FIG. 15B

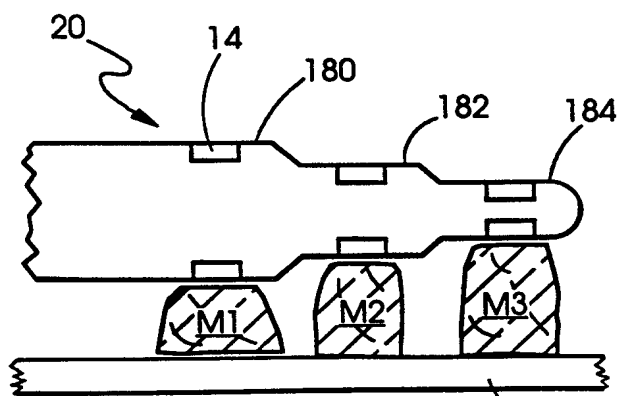


FIG. 16

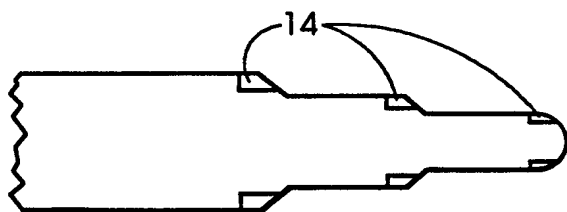


FIG. 16A

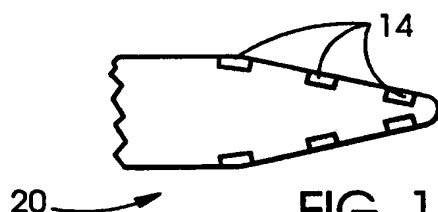


FIG. 16B

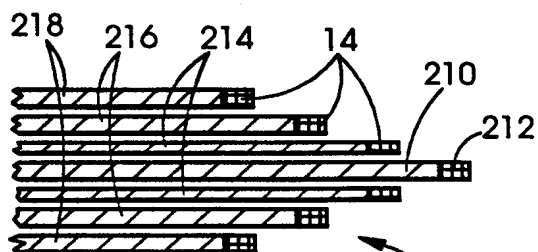


FIG. 17

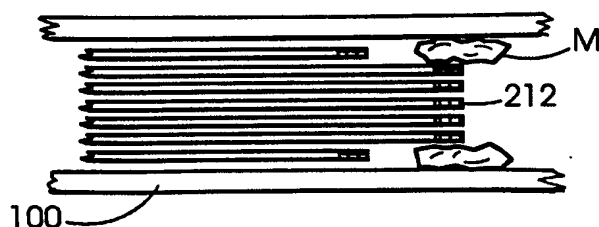


FIG. 17A

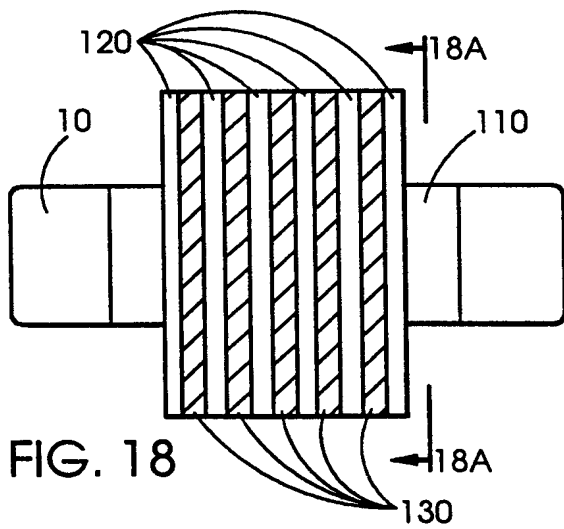


FIG. 18

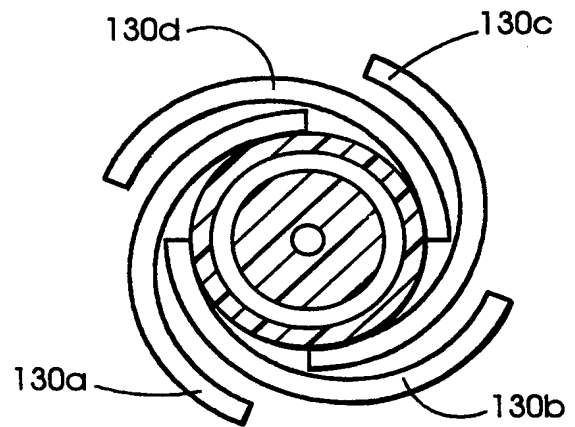


FIG. 18A

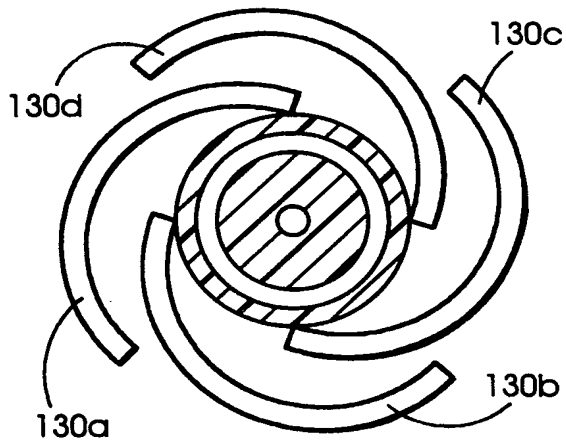


FIG. 18B

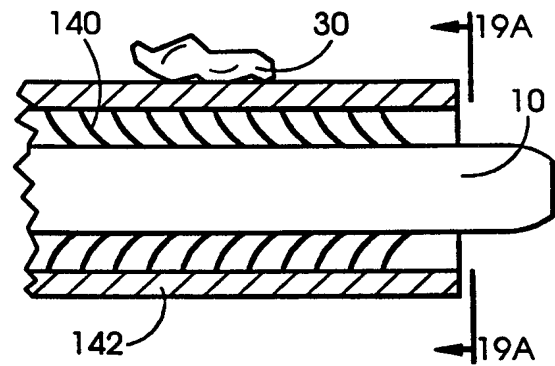


FIG. 19

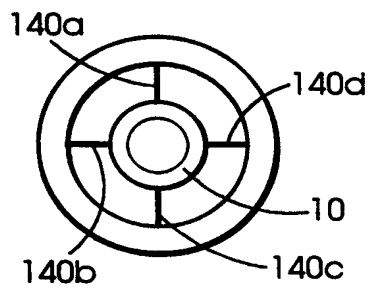


FIG. 19A

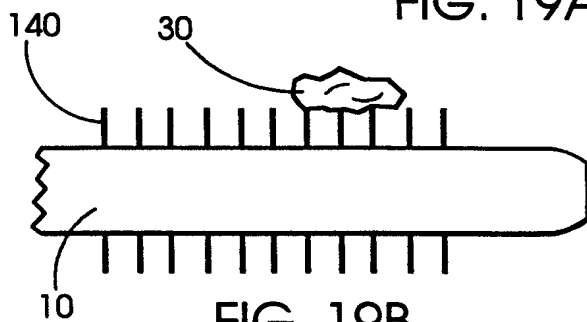


FIG. 19B

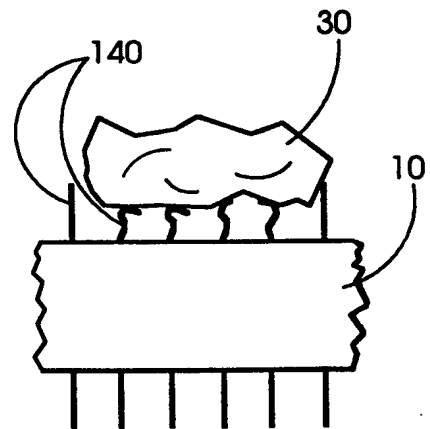


FIG. 19C

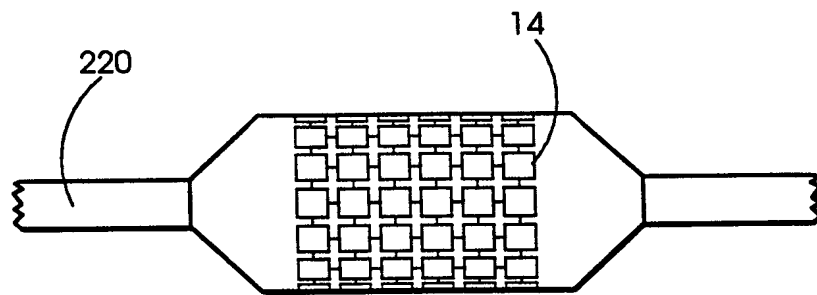


FIG. 20

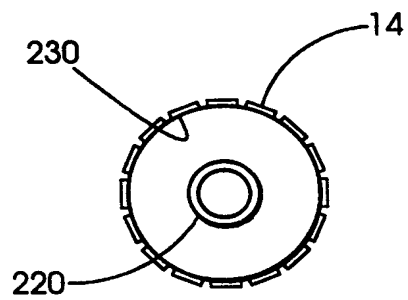


FIG. 20A

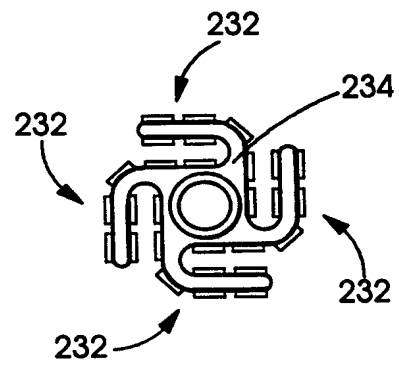


FIG. 20B

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/13382

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 17/22

US CL : 606/159, 170, 171

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/159, 170, 171

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,429,136 A (MILO et al.) 04 July 1995, entire document.	1-37
A	US 5,556,405 A (LARY) 17 September 1996, entire document.	1-37



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

22 SEPTEMBER 1998

Date of mailing of the international search report

22 OCT 1998

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

KEVIN TRUONG

Telephone No. (703) 308-3767